ANDA 75-011 December 22, 1998

ESI Lederle, Inc.
Attention: Nicholas Tantillo
401 N. Middletown Road
Pearl River, NY 10965-1299

Dear Sir:

This is in reference to your abbreviated new drug application dated November 27, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Buspirone Hydrochloride Tablets USP, 5 mg and 10 mg.

Reference is also made to your amendments dated January 9, January 22, March 27, April 1, November 4, 1997 and April 13, June 26, September 16, November 23, and November 30, 1998.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacturing and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application is subject to periods of patent protection which expire on May 22, 2000, (patent 4,182,763, the '763 patent) and May 14, 2008, (patent 5,015,646, the '646 patent). Your application contains a Paragraph IV Certification to the '646 patent under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received.

You have notified FDA that ESI Lederle, Inc. has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement against the '646 patent was brought against ESI Lederle, Inc. within the statutory forty-five day period. In addition, your application contains a Paragraph III Certification to the '763 patent under Section 505(j)(2)(A)(vii)(III) of the Act. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the period has expired, i.e., currently May 22, 2000.

Please provide the Agency, at least 60, but not more than 90 days prior to the expiration of the '763 patent, an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved and should include updated information such as final printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant change in the conditions outlined in this abbreviated application requires Agency approval before the change may be made effective.

Prior to the issuance of a final approval letter by the Agency, your product will **not** be deemed approved for marketing under 21 U.S.C. 355 and not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to May 22, 2000, you should amend your application accordingly.

At the time you submit any amendments, you should contact Mr. Joseph Buccine, Project Manager, at (301) 827-5754, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 311(d).

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research